



PATENT
Docket No. H 3630 PCT/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of Panzer, et al.

Serial No. 09/830,918

Filed: 08/13/01

Examiner: Shaojia A. Jiang, Ph.D,

Art Unit: 1617

TITLE: ALCOHOL-COMPATIBLE CHITOSAN SALTS AND COSMETIC PREPARATIONS
CONTAINING THE SAME

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July 21, 2003
Date

A. R. Ettelman
Aaron R. Ettelman
(Reg. No. 42,516)
Attorney for Applicant(s)
(610) 278-4930

Cognis Corporation, Patent Dept.
2500 Renaissance Boulevard, Suite 200
Gulph Mills, PA 19406

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BY: Rose A. Stowe DATE: July 21, 2003
Rose A. Stowe

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Patent Application of	: Group Art Unit: 1617
	Claudia Panzer, <i>et al.</i>	:
		:
Appln. No.:	09/830,918	: Examiner: Shaojia A. Jiang, Ph.D.
		:
Filed:	August 13, 2001	: Confirmation No.: 5279
		:
For:	ALCOHOL-COMPATIBLE CHITOSAN	: Attorney Docket
	SALTS AND COSMETIC PREP-	: No.: H 3630 PCT/US
	ARATIONS CONTAINING THE SAME	:

APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. §1.192

Pursuant to the Notice of Appeal filed on February 19, 2003, via facsimile, and received by the U.S. Patent & Trademark Office on the same date, Appellants submit herewith a Brief On Appeal under 37 C.F.R. §1.192, appealing the Examiner's final rejection of pending claims 8-27 as set forth in the final Office Action dated November 19, 2002 (Paper No. 9), as maintained in the Advisory Action dated February 4, 2003 (Paper No. 11). This Brief On Appeal is being timely filed as a Petition for a three-month extension of time, up to and including July 21, 2003, (July 19, 2003 being a Saturday), including an authorization to charge fees, is being submitted herewith.

Appellants respectfully request consideration by the honorable Board of Patent Appeals and Interferences and reversal of the Examiner's rejection of all pending claims based on the arguments set forth in the attached brief.

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TABLE OF CONTENTS

Table of Contents	2
Real Party in Interest	3
Related Appeals and Interferences	3
Status of the Claims	3
Status of Amendments	3
Summary of Invention	4
Issues	5
Grouping of the Claims	5
Argument	5
I. The Examiner's Rejection Under 35 U.S.C. §103(a) is Improper	5
A. The Rejection of Claims 8-27 Over Wachter, Yu & Keil	5
B. Appellants' Traversal	6
C. Law Regarding <i>Prima Facie</i> Obviousness & Routine Optimization	6
D. Lack of <i>Prima Facie</i> Obviousness with respect to Claims 8-27	7
E. Indicia of Non-Obviousness	9
Conclusion	11
Appendix A - Claims on Appeal	A-1

REAL PARTY IN INTEREST

The real party in interest in the instant appeal is Cognis Deutschland GmbH & Co. KG, a German company having a place of business at Henkelstraße 67, 40589 Düsseldorf, Germany.

RELATED APPEALS AND INTERFERENCES

Appellants are not aware of any related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

STATUS OF THE CLAIMS

Claims 8-27 are pending in the instant application on appeal. All of the pending claims are the subject of the instant appeal.

Claims 8-27 stand finally rejected under 35 U.S.C. §103(a), as being unpatentable over PCT Publication No. WO96/16991 of Wachter, *et al.*, (hereinafter referred to as "Wachter"), in view of U.S. Patent No. 5,547,988 of Yu, *et al.*, (hereinafter referred to as "Yu"), further in view of U.S. Patent No. 5,690,924 of Keil, *et al.*, (hereinafter referred to as "Keil"), for the reasons of record set forth in Paper No. 9 and Paper No. 11.

STATUS OF AMENDMENTS

No amendments have been filed in the instant application on appeal subsequent to the Examiner's final rejection of claims 8-27. Appellants' Request for Reconsideration After Final, filed on January 21, 2003 ("the Request for Reconsideration After Final"), has been considered but was not deemed to place the instant application in a condition for allowance, as indicated in Paper No. 11. An appendix containing a copy of the claims involved in the appeal, in accordance with 37 C.F.R. §1.192(c)(9), is attached as Appendix A.

SUMMARY OF THE INVENTION

Appellants have surprisingly discovered that certain chitosan salts exhibit exceptionally high ethanol compatibility. (*See*, Appellants' Specification, p. 2, lines 8-9). The superior ethanol compatibility exhibited by these chitosan salts allows for the production of predominantly alcohol-based formulations, such as hair sprays and hair gels. (*See*, Appellants' Spec., p. 2, lines 8-11). Cosmetic preparations in accordance with the claimed invention exhibit improved properties such as, for example, improved setting and consistency. (*See*, Appellants' Spec., p. 2, lines 11-19). As explained in Appellants' Specification, typical prior art chitosan products, such as chitosans in glycolic acid solutions, do not possess a high degree of ethanol compatibility and are not suitable for use in cosmetic preparations with high ethanol content. (*See*, Appellants' Spec., p. 1, lines 7-15). Accordingly, Appellants' claimed invention is directed to high ethanol content cosmetic preparations containing the claimed ethanol-compatible chitosan salts. Appellants' invention is a significant and unexpected improvement over the prior art.

To be more specific, one embodiment of Appellants' claimed invention is directed to cosmetic preparations comprising: (a) ethanol in an amount of from 70 to 90% by weight; and (b) a neutralization product of a chitosan and an acid selected from the group consisting of lactic acid, pyrrolidone carboxylic acid, nicotinic acid, hydroxyisobutyric acid, hydroxyisovaleric acid and mixtures thereof, wherein the neutralization product is present in an amount of from 0.01 to 5% by weight.

Cosmetic preparations in accordance with the claimed invention exhibit significant improvement over the prior art. Appellants have shown that a hair setting composition containing one of the ethanol-compatible chitosan salts, namely chitosan hydroxyisovalerate, in 90% by weight ethanol achieves a flexural strength of 110%, whereas a less ethanol-compatible chitosan salt, namely chitosan glycolate, in a predominantly aqueous solution achieves only a 50% flexural strength rating. (*See*, Appellants' Spec., p. 13, lines 1-5).

ISSUES

- (1) Is the combination of Wachter, Yu and Keil, which fails to teach or suggest the claimed amounts of ethanol, insufficient to establish a *prima facie* case of obviousness with respect to the claimed invention?
- (2) Even if a *prima facie* case of obviousness could be established based upon the teachings of the cited combination, does Appellants' showing of unexpected and significantly improved results with respect to the flexural strength of the claimed compositions overcome such a *prima facie* case of obviousness?

GROUPING OF THE CLAIMS

All of the pending claims stand or fall together for the purposes of the instant appeal.

ARGUMENT

I. The Examiner's Rejection Under 35 U.S.C. §103(a) is Improper

A. The Rejection of Claims 8-27 Over Wachter, Yu & Keil:

In Paper No. 11, the Examiner maintains the rejection of claims 8-27 under 35 U.S.C. §103(a), as being unpatentable over Wachter, in view of Yu, further in view of Keil, for the reasons of record set forth in Papers No. 6, 9 & 11. It should be noted that all references herein to Wachter, as well as in Papers No. 6 & 9 and in Appellants' responses thereto, are directed to the column and line numbers of the English language equivalent of Wachter, U.S. Pat. No. 5,962,663.

The Examiner contends that Wachter discloses a chitosan compound "within the instant claim" which is useful in cosmetic compositions. The Examiner also contends that Wachter discloses cosmetic compositions comprising the chitosans, carboxylic acids and ethanol in amounts of from 10-15%. The Examiner contends that Yu discloses topical compositions containing 2-hydroxycarboxylic acids, chitosan and 40% ethanol. The Examiner contends that Keil discloses a hair treatment composition containing chitosan, 2-pyrrolidone carboxylic acid and 40-50% ethanol. The Examiner acknowledges that the cited references fail to teach compositions having the claimed amount of ethanol.

Nonetheless, the Examiner argues that it would have been obvious to one of ordinary skill in the art to “employ the particular amount (70-90% by weight) of ethanol in the cosmetic compositions”, because “ethanol in 10-15% or 40-50% is known to be used in the cosmetic compositions comprising . . . chitosan and carboxylic acids . . . based on the prior art.” (See, Paper No. 6, pp. 3-4 (*emphasis in original*)). The Examiner argues that one of ordinary skill in the art would have been motivated to optimize the amount of ethanol to 70-90% by weight. On this basis the Examiner maintained that the claimed invention is obvious.

In Paper No. 11, the Examiner summarily rejects Appellants’ arguments set forth in the Request for Reconsideration After Final and concludes simply, without any additional comment, that “motivation to combine the teachings of the prior art cited herein to make the present invention is seen.” (See, Paper No. 11, p. 2). Additionally, in Paper No. 11, the Examiner contends that Appellants have not provided sufficient evidence of nonobviousness, alleging that there is no comparison of the invention to the cited prior art. (See, *id.*).

B. Appellants’ Traversal:

Appellants respectfully traversed the Examiner’s rejection in the Request for Reconsideration After Final, and initially in Appellants’ Request for Reconsideration, filed on August 26, 2002, in response to Paper No. 6.

Appellants again strenuously, but respectfully, traverse the Examiner’s rejection and the contentions and arguments in support thereof, for the reasons set forth below.

C. Law Regarding Prima Facie Obviousness and Routine Optimization:

It is well-settled that in order to establish a *prima facie* case of obviousness, and thus shift the burden of proving non-obviousness onto Applicants, the Examiner must show all of the following three criteria: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of

success must both be found in the prior art and not in Applicants' Specification. (M.P.E.P. §2143).

Furthermore, it is also well-settled that obviousness arguments based upon “routine optimization” rationales are applicable only where the claimed subject matter is *encompassed* by the prior art. (See, M.P.E.P. §2144.05 II(A)). Moreover, “routine optimization” requires the identification of a result-effective variable. “A particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” (See, M.P.E.P. §2144.05 II(B) *citing In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)).

D. *Lack of Prima Facie Obviousness with respect to Claims 8-27:*

To begin with, Wachter does not teach cosmetic compositions including the claimed components. The citation proffered by the Examiner which allegedly teaches the inclusion of carboxylic acids, simply discloses that among many auxiliary *surfactants* which may be included in the taught cosmetic compositions are “ether carboxylic acids and salts thereof.” (See, Paper No. 6, p. 2, Wachter, col. 4, line 61). This hardly qualifies as teaching neutralization products of chitosans and carboxylic acids, as claimed. Moreover, the only reference to ethanol in Wachter cited by the Examiner is a formulation example in Table 2 of the reference wherein a skin tonic is listed as containing 15% by weight of ethanol in combination with a chitosan compound, but without any carboxylic acid.

Yu discloses, in Example 2 thereof, a composition containing 5 grams of lactic acid in an aqueous/ethanol solution (less than 30% ethanol by weight) wherein 0.3 grams of a chitosan **OR** a polyquat is added as a gelling agent. There is no reference to chitosan salts or neutralization products. Yu specifically teaches that the composition contains 5% 2-hydroxypropionic acid, not a salt and not a neutralization product.

Keil discloses hair treatment compositions. Three examples of the compositions contain a chitosan salt of pyrrolidone carboxylic acid and ethanol in amounts of from 40-50% by weight.

As the Examiner has acknowledged, none of the three references teaches the claimed amount of ethanol. The Examiner argues that the use of the claimed amount is simply a routine optimization. Applicants respectfully disagree with the Examiner's assessment. First, obviousness arguments based upon optimization are applicable only where the claimed subject matter is encompassed by the prior art. (*See*, M.P.E.P. §2144.05 II(A)). In the instant application, the claimed range of ethanol in the compositions according to the present invention is from 70 to 90% by weight. The cited references teach amounts of ethanol of 15%, 40% and 50% by weight. A range of from 70 to 90% by weight is not encompassed by the amounts of ethanol disclosed in the cited references. There is no teaching or suggestion to use greater amounts of ethanol. The Examiner has not cited any portion of any of the cited references which provides the supposed motivation to use increased amounts of ethanol. Moreover, the Examiner has not indicated any portion of the references which recognizes an increased ethanol-compatibility in any of the claimed chitosan salts.

Second, "routine optimization" requires the identification of a result-effective variable. "A particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." (*See*, M.P.E.P. §2144.05 II(B) *citing In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)). Nothing in the cited references recognizes ethanol concentration as a result-effective variable. The Examiner has not cited any portion of any of the references as teaching, or even suggesting that it would be desirable to increase the amount of ethanol beyond the taught amounts which are outside Appellants' claimed range.

Nothing in any of the cited references teaches or suggests a cosmetic preparation comprising: (a) ethanol in an amount of from 70 to 90% by weight; and (b) a neutralization product of a chitosan and an acid selected from the group consisting of lactic acid, pyrrolidone carboxylic acid, nicotinic acid, hydroxyisobutyric acid, hydroxyisovaleric acid and mixtures thereof, wherein the neutralization product is present in an amount of from 0.01 to 5% by weight. There is simply no teaching to use such large amounts of ethanol. The largest amount taught is 50% by weight in a single example. Prior to Applicants' invention it was unknown that such

large amounts of ethanol could be used with chitosan, as the increased ethanol-compatibility of certain chitosan salts had yet to be discovered. Applicants discovered that the claimed neutralization products can be advantageously combined with large amounts of ethanol.

Moreover, none of the cited references contains any teaching or suggestion which would motivate one of ordinary skill in the art to modify the teachings of the prior art to utilize significantly greater amounts of ethanol than taught in the cited references. Motivation for modification must suggest a desirability to the modification. None of the references contains any such teaching.

Finally, given that neither reference teaches or suggests the claimed composition, and that neither reference suggests a modification necessary to arrive at the claimed invention, one of ordinary skill in the art would find no reasonable expectation of success in such a deviation based upon the teachings of the references.

Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, as none of the three criteria necessary to establish a *prima facie* case of obviousness has been satisfied. Thus, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

E. Indicia of Non-Obviousness:

Moreover, even if it were assumed, for argument's sake, that a *prima facie* case of obviousness could be established based upon the cited references, any such *prima facie* case of obviousness would be overcome by Appellants' showing of significant and unexpected improvement over the prior art. Appellants respectfully submit that the evidence presented within the Specification is sufficient to rebut the alleged *prima facie* case of obviousness.

Appellants have shown that cosmetic preparations in accordance with the claimed invention, *i.e.*, those which contain (a) ethanol in an amount of from 70 to 90% by weight and (b) certain chitosan neutralization products, exhibit significant improvement over the prior art in terms of flexural strength achieved when they're applied to keratin fibers (hair setting strength). The increased ethanol compatibility of the claimed chitosan salts is surprising and unexpected. (*See*, Appellants' Spec., p. 2, lines 8-11). As pointed out by Appellants, prior art chitosan

formulations did not contain large amounts of ethanol as most chitosan salts do not exhibit such high ethanol-compatibility.

In Appellants' Specification, it is shown that compositions in accordance with the claimed invention more than double the flexural strength of ordinary prior art chitosan containing hair treatments. In Appellants' Examples, which begin at page 12, line 28 of the Specification, a prior art, predominantly aqueous preparation containing 0.2% by weight chitosan glycolate is compared to a composition containing 0.2% by weight chitosan hydroxyisovalerate and 90% by weight ethanol. As set forth in the Examples, the chitosan glycolate solution achieved a flexural strength of 50% whereas the high ethanol/chitosan hydroxyisovalerate solution achieved a flexural strength of 110%. (*See*, Appellants' Spec., p. 13, lines 1-5). Appellants submit that this is indeed a significant improvement over the prior art.

The Examiner has argued in Paper No. 11, that Appellants' evidence of improved results is insufficient because the invention is not compared to the prior art. Appellants respectfully submit that such a comparison is impossible because the invention did not exist in the prior art. None of the cited references teach the claimed amounts of ethanol. A comparison as indicated by the Examiner would amount to comparing the invention to itself, not the prior art.

Section 716.02(b) of the M.P.E.P., which is specifically related to the burden of proof concerning allegations of unexpected results, clearly indicates that both direct **and indirect** comparisons with the prior art may be made. Furthermore, the Federal Circuit has held that "the PTO **must** consider comparative data in the specification in determining whether the claimed invention provides unexpected results." (*In re Soni*, 34 USPQ.2d 1684, 1687 (Fed. Cir. 1995) (*emphasis added*), citing *In re Margolis*, 228 USPQ 940 (Fed. Cir. 1986)). The Federal Circuit also held that, "when an applicant demonstrates *substantially* improved results, . . ., and *states* that the results were *unexpected*, this should suffice to establish unexpected results *in the absence of* evidence to the contrary." (*Soni*, at 1688 (*emphasis in original*)).

Appellants submit that significantly improved results shown by indirect comparison, as set forth in the Specification, along with Appellants' statement that such improved results are unexpected, satisfy the required burden under Section 716.02(b) of the M.P.E.P. and *Soni*, absent evidence to the contrary.

As mentioned above, Appellants' Specification states that the significantly improved ethanol-compatibility of the claimed chitosan salts is surprising. The unexpected increase in ethanol-compatibility allows for the preparation of high ethanol content compositions which achieve significantly increased flexural strength. The results set forth in the Examples of the Specification clearly evidence significant improvement.

It is submitted that Appellants' showing of unexpected and improved results sufficiently rebuts any alleged *prima facie* case of obviousness. Thus, Appellants respectfully request reversal of the Examiner by the Honorable Board and withdrawal of the rejection under 35 U.S.C. §103(a), at least with respect to claim 14.

CONCLUSION

In view of the arguments set forth above, Appellants submit that the Examiner's rejection under 35 U.S.C. §103(a) is improper in that the Examiner has failed to establish a *prima facie* case of obviousness, and that all claims on appeal patentably distinguish over the prior art of record and known to Appellants, either alone or in combination. Accordingly, Appellants respectfully request that the Board find for Appellants and reverse the Examiner's final rejection.

Respectfully submitted,

CLAUDIA PANZER, et al.

July 21, 2003
(Date)

By: _____

AARON R. ETTELMAN

Registration No. 42,516

COGNIS CORPORATION

2500 Renaissance Blvd., Suite 200

Gulph Mills, PA 19046

Telephone: (610) 278-4930

Facsimile: (215) 278-4971

E-Mail: AARON.ETTELMAN@COGNIS-US.COM

ARE:are

APPENDIX A

Claims On Appeal:

1. CANCELED
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8. A cosmetic preparation comprising:
 - (a) ethanol in an amount of from 70 to 90% by weight; and
 - (b) a neutralization product of a chitosan and an acid selected from the group consisting of lactic acid, pyrrolidone carboxylic acid, nicotinic acid, hydroxyisobutyric acid, hydroxyisovaleric acid and mixtures thereof, wherein the neutralization product is present in an amount of from 0.01 to 5% by weight.
9. The cosmetic preparation according to claim 8, wherein the acid is selected from the group consisting of pyrrolidone carboxylic acid, nicotinic acid, hydroxyisobutyric acid, hydroxyisovaleric acid and mixtures thereof.
10. The cosmetic preparation according to claim 8, wherein the acid is selected from the group consisting of hydroxyisobutyric acid, hydroxyisovaleric acid and mixtures thereof.
11. The cosmetic preparation according to claim 8, wherein the chitosan comprises a partially deacetylated chitin having a degree of deacetylation of from 80 to 88%, an ash content of less than 0.3%, a Brookfield viscosity of less than 5000 mPas, and an average molecular weight within a range selected from the group consisting of 10,000 to 1,000,000 daltons and 100,000 to 5,000,000 daltons.

12. The cosmetic preparation according to claim 11, wherein the chitosan has an average molecular weight of from 10,000 to 1,000,000 daltons.

13. The cosmetic preparation according to claim 11, wherein the chitosan has an average molecular weight of from 100,000 to 5,000,000 daltons.

14. The cosmetic preparation according to claim 9, wherein the chitosan comprises a partially deacetylated chitin having a degree of deacetylation of from 80 to 88%, an ash content of less than 0.3%, a Brookfield viscosity of less than 5000 mPas, and an average molecular weight within a range selected from the group consisting of 10,000 to 1,000,000 daltons and 100,000 to 5,000,000 daltons.

15. The cosmetic preparation according to claim 14, wherein the chitosan has an average molecular weight of from 10,000 to 1,000,000 daltons.

16. The cosmetic preparation according to claim 14, wherein the chitosan has an average molecular weight of from 100,000 to 5,000,000 daltons.

17. The cosmetic preparation according to claim 8, wherein the neutralization product comprises from 1 to 10% by weight of the chitosan in the acid, based upon the weight of the neutralization product.

18. The cosmetic preparation according to claim 9, wherein the neutralization product comprises from 1 to 10% by weight of the chitosan in the acid, based upon the weight of the neutralization product.

19. The cosmetic preparation according to claim 11, wherein the neutralization product comprises from 1 to 10% by weight of the chitosan in the acid, based upon the weight of the neutralization product.

20. The cosmetic preparation according to claim 14, wherein the neutralization product comprises from 1 to 10% by weight of the chitosan in the acid, based upon the weight of the neutralization product.

21. The cosmetic preparation according to claim 8, wherein the neutralization product comprises from 2 to 5% by weight of the chitosan in the acid, based upon the weight of the neutralization product.

22. The cosmetic preparation according to claim 8, wherein the preparation and at least one propellant gas are contained within a spraying device.

23. The cosmetic preparation according to claim 22, wherein the ratio by weight of the cosmetic preparation to the at least one propellant gas is from 35:65 to 45:55.

24. The cosmetic preparation according to claim 10, wherein the preparation and at least one propellant gas are contained within a spraying device.

25. The cosmetic preparation according to claim 24, wherein the ratio by weight of the cosmetic preparation to the at least one propellant gas is from 35:65 to 45:55.

26. A cosmetic preparation comprising:
- (a) ethanol in an amount of from 70 to 90% by weight; and
 - (b) a neutralization product of a chitosan and an acid selected from

the group consisting of nicotinic acid, hydroxyisobutyric acid, hydroxyisovaleric acid and mixtures thereof, wherein the neutralization product comprises from 2 to 5% by weight of the chitosan in the acid, based upon the weight of the neutralization product, wherein the neutralization product is present in the preparation in an amount of from 0.01 to 5% by weight, based upon the weight of the preparation, and wherein the chitosan comprises a partially deacetylated chitin having a degree of deacetylation of from 80 to 88%, an ash content of less than 0.3%, a Brookfield viscosity of less than 5000 mPas, and an average molecular weight within a range selected from the group consisting of 10,000 to 1,000,000 daltons and 100,000 to 5,000,000 daltons..

27. The cosmetic preparation according to claim 26, wherein the preparation and at least one propellant gas are contained within a spraying device, and wherein the ratio by weight of the cosmetic preparation to the at least one propellant gas is from 35:65 to 45:55.